UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,765	01/29/2002	Nobuyuki Itoh	201130.408D1	9697

500 7590 06/11/2003

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
LI, RUIXIANG	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 06/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/060,765	ITOH ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, 38, 39, and 45, drawn to polynucleotides of SEQ ID NO: 3 or encoding SEQ ID NO: 4 and their fragments, vectors, host cells, and methods of making polypeptides, classified in class 536, subclasses 23.1; class 435, subclasses 320.1, 325, and 69.1.

II. Claims 12-18 and 22, drawn to an isolated polypeptide of SEQ ID NO: 4 and its variants, classified in class 530, subclass 324.

III. Claims 19-21 and 40, drawn to antibodies against SEQ ID NO: 4 or its fragments, classified in class 530, subclass 387.9.

IV. Claims 23-31, 33, and 34, drawn to a method for providing trophic support for cells in a patient in need comprising a polynucleotide encoding SEQ ID NO: 4, classified in class 514, subclass 44.

V. Claim 32, and 35-37, drawn to a method for treatment of a disease in liver, thymus, and testis using a polypeptide of SEQ ID NO: 4, classified in class 514, subclass 2.

VI. Claims 41-51, drawn to polynucleotides of SEQ ID NO: 1 or encoding SEQ ID NO: 2 and their fragments, vectors, host cells, and methods of making polypeptides, classified in class 536, subclasses 23.1; class 435, subclasses 320.1, 325, and 69.1.

VII. Claims 52-56, drawn to an isolated polypeptide of SEQ ID NO: 2 and its variants, classified in class 530, subclass 324.

VIII. Claims 57-59, drawn to antibodies against SEQ ID NO: 2 or its fragments, classified in class 530, subclass 387.9.

2. The inventions are distinct, each from the other for the following reasons. Inventions I-III are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instance case, the different inventions are drawn to completely different products, polynucleotides, polypeptides, and antibodies. These molecules have completely different structures and biological functions which are not interchangeable and which require non-cohesive searches and considerations. For the same reasons, Inventions VI-VIII are unrelated and distinct.

3. Inventions I and VI, Inventions II and VII, and Inventions III and VIII are distinct inventions, because Inventions I and VI are drawn to different polynucleotides (SEQ ID NO: 3 and SEQ ID NO: 1), Inventions II and VII are drawn to different polypeptides (SEQ ID NO: 4 and SEQ ID NO: 2), and Inventions III and VIII are drawn to different antibodies against the polypeptides of SEQ ID NO: 4 or SEQ ID NO: 2. Each sequence represents a structural and functionally distinct entity that is capable of supporting a separate patent. The search and consideration of more than a single sequence constitutes an undue search burden on the office, given the ever-increasing size of the database. Please note that Claim 45 is present in both Group I and Group VI because it recites an isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide of SEQ ID NO: 2 and SEQ ID NO: 4.

3. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instance case the two inventions are drawn to different methods for disease treatment using polynucleotides or polypeptides. The two methods have different procedures and use different compositions (polynucleotides versus polypeptides). Thus, the two methods are exclusive.
4. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides can be used in a materially different process such as detection of gene expression or protein production.
5. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the peptide may be used in a materially different process such as to immunize with.
6. Invention I is an independent invention from V because Invention I is drawn to polynucleotides while Invention V is drawn to a method for disease treatment using a

polypeptide. Invention II is an independent invention from IV because Invention II is drawn to a polypeptide while Invention IV is drawn to a method for disease treatment using a polynucleotide. Invention III is an independent invention from IV and V because Invention III is drawn to antibodies while Inventions IV and V are drawn to methods for disease treatment using either a polynucleotides or a polypeptide. Inventions IV and V are independent inventions from Inventions VI-VIII because Inventions IV and V, which are drawn to methods for disease treatment using either a polynucleotides of SEQ ID NO: 3 or a polypeptide of SEQ ID NO: 4, are distinct from the products of Inventions VI-VIII, which are drawn to a polynucleotide of SEQ ID NO: 1, a polypeptide of SEQ ID NO: 2, and antibodies against the polypeptide of SEQ ID NO: 2 and its fragments.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and the search required for a single group is not required for any other group, restriction for examination purposes as indicated is proper.

9. Group V contains three patentably distinct species, a disease in the liver, a disease in the thymus, and a disease in the testis. The three species are completely different diseases requiring completely different treatment procedures which are not interchangeable and which require non-cohesive searches and considerations. Accordingly, the restriction is proper.

Should applicant elect Group V, applicant is also required to elect a single species of disease for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02 (a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**yvonne.eyler@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
June 7, 2003